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Guidance for the Reregistration of
Pesticide Products Containing
Naptalam as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

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Pesticides

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Guidance for the Reregistration of Pesticide Products Containing Naptalam

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING AS THE ACTIVE INGREDIENT

NAPTALAM/NAPTALAM SODIUM
(030702)

CASE NUMBER 183

CAS 132-66-1

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

March 1985

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(q)) directs EPA to reregister all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers of the active ingredient). End use producers who

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do not qualify for the formulator's exemption* are also required to submit these data.

An end use producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. An end use registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

*The formulator's exemption applies to a registrant of an end use product if the source of his active ingredient(s): (1) is registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregis- tered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Regis- tration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restric- tions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.
* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered. NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.	

I. Regulatory Position and Rationale

A. Introduction

This Registration Standard describes the regulatory position and rationale for all registered manufacturing-use products (MPs) and end-use products (EPs) containing the herbicide naptalam sodium as the sole active ingredient. The Agency bases its position and rationale on an evaluation of all such products and Section 3, 24(c) and intrastate uses for naptalam sodium. End-use products have been included in this Standard because at the time of publication there were no registered MPs. After briefly describing the chemical and its uses, this chapter presents the regulatory position and rationale, the criteria for registration, acceptable ranges and limits, labeling considerations and tolerance reassessment.

B. Use Profile

Naptalam sodium is a pre- or postemergent phthalic acid type herbicide which selectively controls germinating annual grasses and broadleaved weeds. The registered formulations are an emulsifiable concentrate (EC) and a soluble liquid concentrate (SC/L) of 2.0 lbs active ingredient per gallon (23.7% ai), and a granular product (10.8% ai). The Agency has registered naptalam sodium for use on the following sites: soybeans, peanuts, cucurbits (cantaloupe, cucumber, muskmelon, watermelon), cranberries, and woody nursery stock.

Soybeans are the largest naptalam sodium use site. Approximately four percent of the soybean acreage in the United States is treated each year with naptalam sodium. Use on soybeans accounts for 92 percent of the annual naptalam sodium production. Use on peanuts accounts for another 7 percent, and uses on cucurbits, cranberries, and ornamental nursery woody stock account for the balance.

When applied preemergence, naptalam sodium is applied to the soil surface within 48 hours after planting, either as a broadcast or banded spray (liquid formulations) or as a granular herbicide. Naptalam sodium can also be applied as an overtop application when soybeans are about 18 inches tall, or postemergence in cucurbits before the crop starts to vine and before weeds emerge. Only one application is permitted per year, except on cucurbits, where a second application may be used. The application rate for the EC formulation is 2.0-6.0 lbs ai/A, except on ornamental nursery stock, where up to 8.0 lbs ai/A may be used. The application rate for the granular formulation is 4.3 lbs ai/A, except on cranberries, where 8.1 lbs ai/A is used. Naptalam sodium may be applied with ground equipment on all sites, and the EC formulation may be applied from the air on all sites except ornamental nursery stock.

Tank mixes labeled for use with naptalam sodium are: with bensulide in cucurbits;

with dinoseb, metolachlor, benefin, vernolate, trifluralin, and dinitramine, 2,4-DB or dimethylamine salt of 2,4-DB in peanuts; with dinoseb, 2,4-DB, alachlor, metolachlor, metribuzin, oryzalin, or alachlor and metribuzin in soybeans. It is also available as a package mix with dinoseb and 2,4-DB, and has multiple active registrations with chlorpropham (includes the cranberry site) and dinoseb. Tank mixes and other multiple active ingredient products are not covered by the registration standard process at this time.

C. Background and Description of the Chemical

Naptalam sodium is the common name for the herbicide sodium N-1-naphthylphthalamate. The Chemical Abstracts Service (CAS) number for naptalam is 132-66-1, and the EPA Chemical Code number (also known as the Shaughnessy number) is 030703. The trade name for naptalam sodium is Alanap-L®. Naptalam was first developed in 1949 by the Uniroyal Chemical Company. Uniroyal is the only manufacturer of naptalam, and the only registrant of products with naptalam sodium as the sole active ingredient.

Both naptalam and naptalam sodium salt are purple, crystalline solids. They have melting points of 185°C and 234°C, and specific gravities of 1.362 and 1.386, respectively. Solubilities in common solvents (in g/100 ml) are as follows:

<u>Solvent</u>	<u>Naptalam</u>	<u>Naptalam, Sodium</u>
Water	0.02	30.0
Acetone	0.59	1.68
Xylene	*	0.04
Benzene	*	0.05
Hexane	*	*
Chloroform	0.01	*
DMF	3.94	5.53
DMSO	4.31	140.0
Ether	0.11	0.01
2-propanol	0.21	2.09
MEK	0.37	0.59

* Insoluble in this solvent

Naptalam is not stable above pH 9.5 or above 180°C. It tends to form the imide at elevated temperatures. Very hard water and water with low pH may cause precipitation of free acid from solution of naptalam sodium. Naptalam sodium is incompatible with some pesticides. High electrolyte may be a problem in mixtures with soluble fertilizers.

Naptalam is readily absorbed by roots or foliage, and can be translocated from the roots to the leaves. Its mode of action is the blocking of indoleacetic acid (IAA) action.

D. Regulatory Position and Rationale

Based on a review and evaluation of all available data and other relevant information on naptalam, the Agency has made the following determinations:

1. Manufacturing-use and end-use pesticide products containing naptalam sodium as a sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the tables, in order to maintain existing registrations, to permit new EP registrations, or to register technicals or MPs.

Rationale: The Agency's data base on naptalam sodium is not complete. The Agency requires the data specified in Table A to complete its analysis of the risks and benefits associated with continued registration of naptalam sodium products. Under FIFRA, the Agency cannot cancel or withhold registration simply because data are missing or inadequate (see sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time if they will affect the registration(s) of naptalam sodium products.

2. Groundwater monitoring data will not be required at this time.

Rationale: Because it is water soluble, naptalam sodium has some potential to leach into groundwater, but there is virtually no environmental fate data (e.g. leaching, soil metabolism, etc) available, and the Agency has not received any report of naptalam sodium being found in groundwater. Therefore, although groundwater monitoring data are not required at this time, they may be required later, once the Agency has received and reviewed the environmental fate data listed in Table A.

3. The Agency will require registrants to place certain precautionary statements on the labels of MPs and EPs containing naptalam sodium. The specific language of these statements is given in Section G of this Standard.

Rationale: Because of the toxicological properties of naptalam sodium, certain precautionary statements are required on labels as a means of minimizing the exposure of humans and non-target wildlife. For example, eye irritation studies on the rabbit indicate potential for serious eye damage. Therefore the Agency will require label statements warning of the hazard and requiring handlers to wear a face shield or goggles. Section G lists all required statements.

4. The grazing restrictions on current soybean-use labels will be maintained.

Rationale: Until data concerning the existence and persistence of residues on soybeans, soybean forage, and soybean hay have been submitted and analyzed, current grazing restrictions will minimize chances of residues in animal products. Monitoring of residues in soybean forage is required to determine residue levels.

5. Reentry intervals will not be required.

Rationale: The Agency has determined, based on the use patterns and available toxicology data, that the criteria in §158.140 have not been met. When the pesticide is applied to the soil at or immediately following planting, workers entering the field after applications should encounter minimal dermal and inhalation exposure, regardless of what formulation is used. When the pesticide is applied postplant to soybeans, some workers' lower legs could be exposed by brushing against the bean plants. However, because no dermal toxicity data are available, the hazards of such exposure cannot be estimated. Thus, the requirement of a reentry interval at this time would be premature. The Agency will review dermal and inhalation toxicity data as it is received in response to this Standard and the accompanying 3(c)(2)(B) letter, and will determine after that review whether to require a reentry interval.

6. New studies, conducted to fulfill data requirements listed in Table A, must be run using the technical grade of the sodium salt, where the table indicates "TGAI" as the proper test substance. Because there is no registered technical grade in this case, the technical grade will be defined as the purest form of the sodium salt of naptalam resulting from a typical manufacturing process, i.e. the grade of the material immediately prior to the formulation of end-use products. Data from chronic toxicity studies in which the pure acid or salt was used may be used to support registrations if the registrant can properly identify the substance and justify its use. Furthermore, clear identification of all EPs, e.g. the 23.7 percent a.i., et al used as testing materials (and their contaminants) is required before the data obtained can be evaluated. Some current toxicological data gaps may be filled by existing data, if identification of the testing materials is completed by the registrant.

Rationale: The Agency usually requires data on the technical grade of the manufacturing-use product. There is no registered manufacturing-use product in this case; sodium naptalam products are produced via an integrated formulation process. Therefore the appropriate test substance is the purest form of the sodium salt resulting from a typical manufacturing process. Studies using the pure acid or salt may offer sufficient toxicological information to support registration, if the registrant can identify the substance used and justify its use.

7. At least until the required data on plant metabolism and field residues are submitted and reviewed, the Agency will require the labels of all products registered for use on soybeans to bear a statement prohibiting use within ninety days of harvest.

Rationale: The data available on the residues remaining on soybeans up to ninety days post-treatment are insufficient to allow proper evaluation of the potential hazards they pose. Imposition of a ninety-day post-treatment interval will reduce the potential exposure to possibly harmful residue levels.

8. The Agency will not approve additional tolerances for significant new crops until data gaps regarding acute toxicity, teratogenicity, oncogenicity, plant and animal metabolism, storage stability, reproductive effects, and environmental fate are filled. No new tolerances will be granted until the data required to support the new tolerances are submitted.

Rationale: The virtual lack of toxicity and environmental fate data prevent evaluation of the hazards posed by use of naptalam sodium. In the absence of positive evidence of hazard, existing registrations may be maintained, but the increased exposure rates that would result from significant new tolerances and registrations could increase hazards that are as yet unrecognized, due to the extensive data gaps.

E. Criteria for Registration Under This Standard

To be covered by this Standard, products must:

- o contain naptalam sodium as the sole active ingredient, and
- o bear required labeling and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Sections F and G of this document.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it. This includes making a commitment to fill data gaps on a schedule specified by the Agency. Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. Acceptable Ranges and Limits

(Note: At the time of publication of this Standard, no manufacturing-use products (MPs) have been registered for use, nor are any proposed for registration. References to the requirements for MPs refer to any future registrations.)

1. Product Composition Standard

To be fully covered under this guidance document, MPs and EPs must contain naptalam sodium as the sole active ingredient. Each product formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the naptalam products must be substantially similar to that in currently registered products. Any product not meeting these requirements will be considered a new product and will not be registered under this Standard.

2. Acute Toxicity Limits

The Agency will consider registration of MPs and EPs containing naptalam sodium when the product is supported by acute toxicity data and the labeling of the product bears the appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard, MPs containing naptalam sodium must be labeled for formulation into EPs that are to be used for the control of weeds in cranberries, peanuts, soybeans, woody nursery stock, or cucurbits. EPs must be labeled for use on these same commodities.

G. Required Labeling

All technical grade and manufacturing-use products containing naptalam sodium must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements. In addition, the following specific labeling requirements apply:

1. Use Pattern Statements:

Labels of all MPs must bear the statement:

"For formulation into end-use herbicide products intended only for use on soybeans, peanuts, cucurbits, cranberries, or woody nursery stock."

2. Precautionary Statements

Labels of MPs and EPs must bear the statements:

a. Hazards to Humans Statements

"DANGER: Harmful if swallowed. Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear a face shield or goggles. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse." and;

b. Statements of Practical Treatment

"If in eyes: Flush with water for fifteen minutes. Call a physician."

"If swallowed: Call a physician or Poison Control Center. Drink promptly a large quantity of milk, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage."

c. Environmental Hazard Statement

The following specific statements must appear on the labels of all MPs:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

The labels of EPs intended for outdoor use must bear one of the following statements, depending on the formulation of the product:

Granular products must bear the statement:

"Do not apply directly to water. In case of spills, collect for reuse or properly dispose of the granules. Do not contaminate water by cleaning of equipment or disposal of wastes."

Non-granular products must bear the statement:

"Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes."

d. Grazing Restrictions Statement

The labels of all EPs registered for use on peanuts must bear the statement:

"Do not graze or feed forage or hay from treated peanuts to livestock.

The labels of all EPs registered for use on soybeans must bear the statement:

"Do not harvest soybeans or soybean hay earlier than 90 days post-treatment. Do not graze or feed forage or hay from treated fields to livestock."

The labels of all products must bear the appropriate container disposal statement. See Appendix IV-5 of this guidance package.

The required statements listed in this Standard must appear on the labels of all MPs and EPs released for shipment after March 1, 1986. The labels of all MPs and EPs currently in the channels of trade must be modified to include all the listed statements by March 1, 1987. After review of data to be submitted under this Standard, the Agency may impose additional label requirements.

H. Tolerance Reassessment

Tolerances of 0.10 ppm (considered negligible) have been established for the residues of naptalam in or on certain raw agricultural food commodities such as cantaloups, cranberries, cucumbers, muskmelons, peanuts, soybeans, and watermelons. (See 40 CFR 180.297.) An acceptable daily intake (ADI) for man has not been set, because no valid chronic feeding study data are available. A provisional acceptable daily intake (PADI) was set at 0.0375 mg/kg/day, based on a 13-week subchronic dog feeding study with a no effect level (NOEL) of 3000 ppm, and a safety factor of 2000. Based on this PADI, a maximum permissible intake (MPI) was set at 2.25 mg/day for a 60 kg female. However, the study on which the PADI was based has been reclassified Core Supplementary, and no other data are available on which to base a new PADI. Therefore at present there is no valid PADI nor ADI. A new ADI will be calculated when the Agency receives, reviews, and classifies as Core Minimum, a two-year feeding study in rats or a one-year feeding study in dogs.

International Tolerances

The following Canadian tolerances exist for the residues of naptalam. There are no Mexican tolerances or Codex Maximum Residue Limits (MRLs) for residues of naptalam sodium.

<u>COMMODITY</u>	<u>(PPM)</u>
Cantaloups	0.10
Cranberries	0.10
Cucumbers	0.10
Melons	0.10
Soybeans	0.10
Watermelons	0.10

II.

REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following this section list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data^{1/} Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines ^{2/} or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type

^{1/} Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

^{2/} The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases. to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii); and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ^{1/} , ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ³
<u>\$158.120 Product Chemistry</u>				
<u>Product Identity:</u>				
61-1 - Identity of Ingredients	TGAI	Yes	00106268 00106316	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00106268 00106316	Yes ^{4/}
61-3 - Discussion of Formation of Impurities	TGAI	No	-	Yes ^{5/}
<u>Analysis and Certification of Ingredients</u>				
62-1 - Preliminary Analysis	TGAI	No	-	Yes ^{6/}
62-2 - Certification of Ingredient Limits	TGAI	No	-	Yes ^{7/}
62-3 - Analytical Methods to Verify Certified Limits	TGAI	No	-	Yes
<u>Physical and Chemical Characteristics</u>				
63-2 - Color	TGAI	Yes	00029170	No
63-3 - Physical State	TGAI	Yes	00029170 00029183	No

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ¹ / ₂	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under RIFRA Section 3(c)(2)(B)? ³
<u>§158.120 Product Chemistry (continued)</u>				
63-4 - Odor	TGAI	No	-	Yes
63-5 - Melting Point	TGAI	Yes	00029170 00029183	No
63-6 - Boiling Point	TGAI	N/A	-	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Partially	00029170	Yes ⁸ / ₋
63-8 - Solubility	TGAI/PAI	Yes	00029170	No
63-9 - Vapor Pressure	PAI	N/A	-	No
63-10 - Dissociation constant	TGAI, PAI	No	-	Yes
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes ⁹ / ₋

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPHTALAM/NAPHTALAM SODIUM

Data Requirement	Composition <u>1/</u> , <u>2/</u>	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under RIFRA Section 3(c)(2)(B)? <u>3/</u>
<u>§158.120 Product Chemistry</u> (continued)				
63-12 - pH	TAI, PAI	Partially	00029170	Yes <u>10/</u>
63-13 - Stability	TAI	Yes	00029170 00029183	No
<u>Other Requirements:</u>				
64- 1 - Submittal of samples	Choice	No	-	Yes <u>11/</u>

1/ Composition: TAI = Technical grade of the active ingredient; PAI = Pure active ingredient. Choice = Choice of several test substances determined on a case-by-case basis.

2/ A manufacturing-use product (MP) for naptalam has not been registered.

3/ Data must be submitted no later than six months after publication of this Standard, unless otherwise indicated.

4/ The manufacturer/registrant must submit an updated description of the manufacturing process. Information is needed as to whether technical naptalam is produced by a batch or continuous process and details concerning how the registrant produces end-use naptalam [e.g. the identity of the intermediate(s) used in producing naptalam products of relatively high concentrations (> ca 24%)]. Information is also needed on the beginning materials, i.e. the names and addresses of the suppliers and information available from the suppliers concerning the composition of these materials (e.g. the percentage figures for the reactant(s) and their impurities). Registrants must submit information as to whether nitrite nitrogen (NO₂-N) is used in the formulation as a corrosion inhibitor, because of the potential for the formation of nitrosamines. Data must be submitted no later than twelve months after publication of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

\$158.120 Product Chemistry (continued)

- 5/ The registrant must submit a discussion concerning impurities present in naptalam sodium. The discussion must address impurities likely to be present in amounts of 0.1% or more and highly toxic impurities, including those of carcinogenic potential (as designated by the Agency) which may be present at 0.1% or less. Such highly toxic impurities may include (but are not limited to): nitrosamines, 1-naphthylamine, 2-naphthylamine, and the hydroxy derivative of 2-naphthylamine. Data must be submitted no later than twelve months after publication of this Standard.
- 6/ Five current production lots of the TAI must be analyzed for the active ingredient, any impurities >0.1%, and any highly toxic impurities at <0.1%. The analyses for highly toxic impurities must include those discussed under 61-3 (Discussion of the Formation of Impurities) and believed to be present. Two samples from each lot must be analyzed shortly after production, two more after three months, and two more after six months. For nitrosamines, methodology with a sensitivity of 1.0 ppm is needed.
- 7/ A Statement of Certified Limits as described by the Guidelines is required from the manufacturer for each integrated-formulation-system product (IFS-product). For naptalam and the intentionally added ingredients, an upper and lower limit must be certified. For impurities present in amounts >0.1%, and any highly toxic impurities, an upper limit(s) must be certified.
- 8/ The registrant must submit data on the temperature at which the specific gravity was determined.
- 9/ The requirement of data on the octanol/water partition coefficient is conditional. If the salt dissociates, then the data are required.
- 10/ Data are needed on the pH of naptalam, and on the concentration at which the pH of naptalam sodium was determined.
- 11/ Samples are required of both the TAI, ca 200g, and the pure analytical grade of sodium naptalam.

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirements	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.125 Residue Chemistry</u>				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	No	-	Yes ^{3/}
- Livestock	PAIRA	No	-	Yes ^{4/}
171-4 - Residue Analytical Method				
- Plant residues	TGAI	Yes	00015782 00028829 00029180 00029182 00076252 00076255 00089710 00106267 00106284	No ^{5/}
- Animal Residues	TGAI	No	-	No ^{6/}

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Test Requirements	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
158.125 Residue Chemistry (continued)				
171-4 - Storage Stability Data	PAI and metabolites	No	-	Yes ^{7/}
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Crop Group 1 - Legume Vegetables (succulent or dried)				
Crop 1 - Soybeans (including hulls, meal, oil, and soapstock)				
-- Crop field trials	TEP	Yes	00015776 00069142 00106296 00015781 00089708 00106315 00024512 00094846 00106319 00029325 00106269 00106393 00030995 00106274 00108307 00031797 00106284 00108871 00069134 00106293 GS-0183-08	No ^{8/}
Crop Group 2 - Foliage of Legume Vegetables Group				
Crop 1 - Soybean Forage and Hay				
-- Crop field trials	TEP	Partially	00031797 00106293 00106269 00108307 00106284	Yes ^{9/}

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.125 Residue Chemistry (continued)</u>				
Crop Group 3 - Cucurbit Vegetables Group				
Crop 1 - Cucumbers				
-- Crop field trials	TEP	Partially	00106269 00106284 00108308	Yes ^{10/}
Crop 2 - Cantaloupes				
-- Crop field trials	TEP	Partially	00106269 00106284 00108308	Yes ^{11/}
Crop 3 - Watermelons				
-- Crop field trials	TEP	Partially	00106269 00106284 00108308	Yes ^{12/}
Crop 4 - Muskmelons				
-- Crop field trials	TEP	Partially	00106269 00106284 00108308	Yes ^{13/}

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ^{1/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{2/}
<u>\$158.125 Residue Chemistry (continued)</u>				
Crop Group 4 - Small Fruits and Berries Group				
Crop 1 - Cranberries				
-- Crop field trials	TEP	Yes	00106269 GS-0183-09 00106284 GS-0183-10	No ^{8/}
Miscellaneous Commodities				
-- Peanuts (including meal, oil, and soapstock)	TEP	Yes	00031793 00106290 00106041 GS-0183-11 00106269 GS-0183-09	No ^{8/}
-- Peanut Hulls	TEP	Yes	00106041 00106290 00106269 GS-0183-14 00106284 GS-0183-15	No ^{8/}
-- Peanut Forage and Hay	TEP	Partially	00031793 00106269 00106041 00106284	Yes
Meat/milk/poultry/eggs	TEP and metabolites	N/A	-	No ^{14/}

^{1/} Composition: TGA1 = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

^{2/} Data must be submitted no later than twenty-four months after publication of this Standard, unless otherwise indicated.

DATA TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

\$158.125 Residue Chemistry (continued)

- 3/ The registrants can fill this data gap in one of two ways, either by using two ^{14}C -naptalam studies, one with the ring-labeled phthalic acid moiety and the other with a ^{14}C -label in the 1-naphthylamine moiety (isolation and identification of metabolites from mature plant tissues must follow), or by using a double-labeled test material. At least soybeans and a cucurbit must be tested.
- 4/ Data on rat, ruminant, and poultry metabolism (metabolites) are required unless the registrant can show that there are no detectable residues in animal feeds by a sensitive method, or that practical restrictions can be imposed on the use of naptalam which will preclude from animal feeds detectable residues of concern.
- 5/ Additional methodology may be required if metabolites of concern are identified in plant tissues.
- 6/ Additional methodology may be required if residues of concern are identified in animals based on the requested animal metabolism studies, but only if tolerances in meat, milk, or eggs and/or feeding studies are required.
- 7/ The registrant must submit data that show the storage stability of residue samples subjected to the same conditions under which the residue samples collected by the registrant have been stored.
- 8/ Additional residue data may be required if the requested plant metabolism studies reveal additional residues of concern.
- 9/ The registrant must submit data on the residues in soybean forage.
- 10/ A preemergence treatment with an EC, G, or SC/L must be made at 6 lb ai/A followed one month after seeding (or before vine formation) by a postemergence treatment with an EC or SC/L at 4 lb ai/A. Aerial and ground-applied postemergence treatments are required. All residues of concern identified in the requested plant metabolism studies must be determined. Studies must be conducted in CA, FL, NC, TX, MI, NY, and WA.
- 11/ Same as cucumbers (footnote 10) except that tests must be conducted in either CA and IN, or MI, GA, TX, and AZ.
- 12/ Same as cucumbers (footnote 10) except that test sites must be in CA, FL, TX, SC, and MO.
- 13/ Data for cantaloupes, cucumbers, and watermelons will be translated to muskmelons.
- 14/ No tolerances for naptalam residues in animal products have yet been established because no detectable residues were expected in or on feed items.

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ^{1/}	Use Pattern ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.130 Environmental Fate</u>					
<u>DEGRADATION STUDIES-LAB:</u>					
161-1 - Hydrolysis	TCAI OF PAIRA	A, B, C, G	No	-	Yes ^{4/}
<u>Photodegradation</u>					
161-2 - In water	TCAI OF PAIRA	A, B, C, G	No	-	Yes ^{4/}
161-3 - On soil	TCAI OF PAIRA	A, G	No	-	Yes ^{4/}
161-4 - In air	TCAI OF PAIRA	N/A ^{5/}	-	-	No
<u>METABOLISM STUDIES-LAB:</u>					
162-1 - Aerobic Soil	TCAI OF PAIRA	A, B	No	-	Yes ^{6/}
162-2 - Anaerobic Soil	TCAI OF PAIRA	N/A ^{7/}	No	-	No
162-3 - Anaerobic Aquatic	TCAI OF PAIRA	C, G	No	-	Yes ^{6/}
162-4 - Aerobic Aquatic	TCAI OF PAIRA	C	No	-	Yes ^{8/}

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ^{1/}	Use Pattern ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>158.130 Environmental Fate (continued)</u>					
<u>MOBILITY STUDIES:</u>					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A, B, C, G	No	-	Yes ^{4/}
163-2 - Volatility (Lab)	TEP	N/A ^{5/}	-	-	No
163-3 - Volatility (Field)	TEP	N/A ^{5/}	-	-	No
<u>DISSIPATION STUDIES-FIELD:</u>					
164-1 - Soil	TEP	A, B	No	-	Yes ^{6/}
164-2 - Aquatic (Sediment)	TEP	C	No	-	Yes ^{9/}
(Water)	TEP	C	No	-	Yes ^{9/}
164-3 - Forestry	TEP	N/A ^{10/}	-	-	No
164-4 - Combination and Tank Mixes		N/A ^{11/}	-	-	No
164-5 - Soil, Long-term	TEP	Reserved ^{12/}	-	-	-

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ¹ / Pattern ² / Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ³ / Yes ⁶ /
<u>\$158.130 Environmental Fate</u>				
<u>ACCUMULATION STUDIES:</u>				
165-1 - Rotational Crops (Confined)	PAIRA A,C	No	-	Yes ⁶ /
165-2 - Rotational Crops (Field)	TEP Reserved ¹³ /	-	-	-
165-3 - Irrigated Crops	TEP N/A ¹⁴ /	-	-	No
165-4 - In Fish	TGAI or PAIRA A,B,C	No	-	Yes
165-5 - In Aquatic Non-Target Organisms	TEP C ¹⁵ /	No	-	Yes
<u>\$158.140 Reentry Protection</u>	TEP N/A ¹⁶ /	-	-	No

¹/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled;
TEP = Typical end-use product.

²/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

\$158.130 Environmental Fate
(continued)

- 3/ Unless otherwise indicated, data must be submitted no later than six months after publication of this Standard.
- 4/ These data have been required under a data call-in program. The data must be submitted no later than nine months after receipt of the data call-in notice, which was mailed October 31, 1984.
- 5/ No data are required because of use pattern and low vapor pressure (volatility) of naptalam sodium salt.
- 6/ These data have been required under a data call-in program. The data must be submitted no later than two years after the receipt of the data call-in notice, which was mailed October 31, 1984.
- 7/ Anaerobic aquatic replaces anaerobic soil - anaerobic aquatic required.
- 8/ Data must be submitted no later than twenty-four months after publication of this Standard.
- 9/ These data have been required under a data call-in program. The data must be submitted no later than two years after receipt of the data call-in notice, which was mailed October 31, 1984.
- 10/ No forestry use.
- 11/ Registration Standards do not address combinations and tank mixes in most cases.
- 12/ If 50% dissipation reached by time of subsequent (label) application, no long-term study required. (based on aerobic soil metabolism or field dissipation studies.) If data are required, they must be submitted no later than three years after publication of this Standard.
- 13/ Required if significant residue(s) of concern are detected in the confined study.
- 14/ Water used to flood cranberries is not utilized for other crops.
- 15/ Cranberry use has aquatic impact; direct discharge into water accessible to wildlife, birds, fish or aquatic organisms.
- 16/ Re-entry not triggered by this pesticide.

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPHTALAM/NAPHTALAM SODIUM

Data Requirement	Composition ¹ / Patterns ²	Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ³
<u>\$158.135 Toxicology</u>					
<u>ACUTE TESTING:</u>					
81-1 - Oral Toxicity - Rat	TGAI	A, B	Yes	00029172 00076205	No
81-2 - Dermal Toxicity	TGAI	A, B	No	-	Yes
81-3 - Inhalation Toxicity - Rat	TGAI	A, B	No	-	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	N/A	N/A	-	No ⁴
<u>SUBCHRONIC TESTING:</u>					
82-1 - 90-Day Feeding - Rodent	TGAI	A	No	-	Yes ⁵
Non-rodent	TGAI	A	No	-	Yes ⁵
82-2 - 21-Day Dermal	TGAI	N/A	No	-	Reserved ⁶
82-3 - 90-Day Dermal	TGAI	N/A	No	-	Reserved ⁶
82-4 - 90-Day Inhalation - Rat	TGAI	N/A	No	-	Reserved ⁶
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI	N/A	No	-	No ⁴

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPHTALAM/NAPTALAM SODIUM

Data Requirement	Composition ¹ / Patterns ² / Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ³ / Yes ⁵ / Yes ⁷ / Yes ⁸ / Yes ⁹ / Yes ¹⁰ / Yes ¹¹ / Yes ¹² /
<u>\$158.135 Toxicology (continued)</u>				
<u>CHRONIC TESTING:</u>				
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI A	No	-	Yes ⁵ / Yes ⁷ / Yes ⁸ / Yes ⁹ / Yes ¹⁰ / Yes ¹¹ / Yes ¹² /
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI A	Partially	GS-0183-15	Yes ⁷ / Yes ⁸ / Yes ⁹ / Yes ¹⁰ / Yes ¹¹ / Yes ¹² /
83-3 - Teratogenicity - 2 species	TGAI A,B	Partially	00106320	Yes ⁸ / Yes ⁹ / Yes ¹⁰ / Yes ¹¹ / Yes ¹² /
83-4 - Reproduction - 2-generation	TGAI A,B	No	-	Yes ⁹ / Yes ¹⁰ / Yes ¹¹ / Yes ¹² /
<u>MUTAGENICITY TESTING</u>				
84-2 - Gene Mutation	TGAI A,B	Partially	00072153	Yes ¹⁰ / Yes ¹¹ / Yes ¹² /
84-2 - Chromosomal Aberration	TGAI A,B	No	-	Yes ¹¹ / Yes ¹² /
84-2 - Other Mechanisms of Mutagenicity	TGAI A,B	No	-	Yes ¹² /

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPHTALAM/NAPHTALAM SODIUM

Data Requirement	Composition ^{1/} Pattern ^{2/}	Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under RIFRA Section 3(c)(2)(B)?
<u>\$158.135 Toxicology (continued)</u>					
<u>SPECIAL TESTING:</u>					
85-1 - General Metabolism	PAI or PAIRA	A	No	-	Yes

- 1/ Composition: TCAI = technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabeled; Choice = Choice of several test substances determined on a case-by-case basis.
- 2/ Possible use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
- 3/ Unless otherwise specified, data must be submitted no later than six months after the publication of this Standard.
- 4/ Data are not required.
- 5/ Data are required for a rodent (preferably the rat) and a non-rodent (preferably the dog) species. Data must be submitted no later than twelve months after publication of this Standard.
- 6/ Requirement is contingent upon the outcome of the worker exposure analysis, if needed.
- 7/ The listed study fulfills part of the data requirement, because it is a valid study using mice. A second study using another species (preferably the rat) is required. These data were required under a data call-in notice mailed October 31, 1984. Data must be submitted no later than four years after receipt of that notice.
- 8/ The listed study fulfills part of the data requirement, because it is a valid study using rats. A second study using rabbits, is required. These data were required under a data call-in notice mailed October 31, 1984. These data must be submitted no later than twenty-six months after receipt of that notice.
- 9/ Data must be submitted no later than twenty-two months after the publication of this Standard.

\$158.135 Toxicology
(continued)

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

- 10/ Testing is required in mammalian cells (mouse Lymphoma L5178Y; or CHO, HGPRT locus). Data must be submitted no later than ten months after publication of this Standard.
- 11/ Testing is required in an in vitro system (SCE in CHO cells or cells or other mammalian cell lines); and in an in vivo system (dominant lethal test in rodents). Data must be submitted no later than ten months after the publication of this Standard.
- 12/ Testing is required for DNA repair in mammalian cells. Data must be submitted no later than ten months after the publication of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ^{1/}	Use Pattern ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.145 Wildlife and Aquatic Organisms</u>					
<u>AVIAN AND MAMMALIAN TESTING</u>					
71-1 - Avian Acute Oral Toxicity	TGAI	A, B	Yes	CS-0183-16	No
71-2 - Avian Dietary Toxicity	TGAI	A, B	Yes	00108853	No
a) Waterfowl		A, B	Yes	00082969	No
b) Upland Game Bird					
71-3 - Wild Mammal Toxicity	TGAI	N/A			
71-4 - Avian Reproduction	TGAI	A	No	-	Reserved ^{4/}
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A, B	No	-	No
<u>AQUATIC ORGANISM TESTING</u>					
72-1 - Acute Toxicity to Freshwater Fish	TGAI				
a) Warmwater Species		A, B	Yes	00070193	No
b) Coldwater Species		A, B	Yes	00024161 ^{5/} 00070193	No
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A, B	Yes	00082971	No
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI				
a) Shrimp		A ^{6/}	No	-	Reserved ^{4/}
b) Marine fish		A ^{6/}	No	-	Reserved ^{4/}
c) Oyster		A ^{6/}	No	-	Reserved ^{4/}

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ^{1/} Pattern ^{2/}	Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.145 Wildlife and Aquatic Organisms (continued)</u>					
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A	No	-	Reserved ^{4/}
72-5 - Fish - Life-Cycle	TGAI	A	No	-	Reserved ^{4/}
72-6 - Aquatic Organism Accumulation	TGAI	A	No	-	Reserved ^{4/}
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TGAI	A	No	-	Reserved ^{4/}

^{1/} Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; TEP = Typical end-use product. Unless otherwise specified, "active ingredient" refers to the sodium salt of naptalam.

^{2/} The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor

^{3/} Unless otherwise specified, data must be submitted no later than six months after publication of this Standard.

^{4/} Reserved pending development of environmental fate information.

^{5/} This study does not fulfill guideline requirement on its own. It must be used in conjunction with other studies.

^{6/} Support for soybeans - a crop grown extensively in coastal counties.

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

Data Requirement	Composition ^{1/}	Use Pattern ^{2/}	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? ^{3/}
<u>\$158.155 Nontarget Insect</u>					
<u>NONTARGET INSECT TESTING -</u>					
Pollinators:					
141-1 - Honey bee acute contact toxicity	TCAI	A, B	Yes	00028772	No
141-2 - Honey bee toxicity of residues on foliage	TEP	A, B	No	-	No ^{4/}
141-4 - Honey bee subacute feeding study	Reserved ^{5/}				
141-5 - Field testing for pollinators	TEP	A, B	No	-	No ^{4/}
<u>NONTARGET INSECT TESTING - AQUATIC INSECTS:</u>					
142-1 - Acute toxicity to aquatic insects	Reserved ^{6/}				
142-2 - Aquatic insect life-cycle study	Reserved ^{6/}				
142-3 - Simulated or actual field testing for aquatic insects	Reserved ^{6/}				
143-1 - NONTARGET INSECT TESTING	Reserved ^{6/}				
143-3 PREDATORS AND PARASITES	Reserved ^{6/}				

TABLE A
GENERIC DATA REQUIREMENTS FOR NAPTALAM/NAPTALAM SODIUM

\$158.155 Non-target Insect Data
(continued)

- 1/ Composition: TGA1 = Technical grade of the active ingredient; TEP = Typical end-use product.
- 2/ The use pattern codes are as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
- 3/ Data must be submitted no later than six months after publication of this Standard, unless otherwise indicated.
- 4/ As data from the acute study indicate low toxicity to bees, no further testing is required.
- 5/ Requirement reserved pending Agency development of test methodology.
- 6/ Reserved pending Agency decision as to whether the data requirement should be established.

III. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. **PRODUCT NAME** - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. **COMPANY NAME AND ADDRESS** - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. **NET CONTENTS** - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

<u>Size of Label on Front Panel in Square Inches</u>	<u>Signal Word Minimum Type Size All Capitals</u>	<u>"Keep Out of Reach of Children" Minimum Type Size</u>
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

IV. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Robert Taylor, Product Manager
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-1650

A. For Manufacturing Products (MP) containing (name of pesticide) as an active ingredient.

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data.

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to PR Notice 84-4 (enclosed) for latest requirements.

3. Within the times set forth in Table A, all generic data must be submitted.

Note: If for any reason any required test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager.

B. For Manufacturing Use Products containing (name of pesticide) in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within the times set forth in Table A, all generic data must be submitted.

Note: If for any reason any required test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager.

C. For End Use Products containing (name of pesticide) alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data. (Refer to Table C).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to PR Notice 84-4 (enclosed) for latest requirements.

3. For those end use product registration that are not eligible for the formulator's exemption, submit all generic data within the time set forth in Table A.

D. For intrastate products containing (name of pesticide) either as the sole active ingredient or in combination with other active ingredients

Guide to Use of This Bibliography

1. **CONTENT OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

- a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.
- b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

APPENDIX II-2

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting
Registrations Under the Naptalam/Naptalam Sodium Standard

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- 00029183 Feldman, A.W.; Reynolds, P.M., comp. (19??) A Technical Summary on Alanap, a Pre-emergence Herbicide and Growth Regulant. Naugatuck, Conn.: United States Rubber. (Alanap summary no. 6B; also in unpublished submission received Dec 12, 1967 under 400-49; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:009021-P)
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- GS-0183-01 Pesticide Petition OP0904 (Acc. No. 116364) Section D: "Determination of Alanap® Residues in Crops" by J.R. Lane.
- GS-0183-02 Pesticide Petition OP2321 (Acc. No. 238629) Section D: "Alanap® General Residue Method" by J.R. Lane
- GS-0183-03 FDA Pesticide Analytical Manual, Volume II, July 1967
- GS-0183-04 Pesticide Petition OP0904 (Acc. No. 116364) Section D: "The Determination of Phthalic Acid Residues in Cranberries: by J.R. Lane
- GS-0183-05 Pesticide Petition OP0904 (Acc. No. 116364) Section D: "Determination of Phthalic Acid Residues in Watery Crops and/or Purified Vegetable Oils" by J.R. Lane
- GS-0183-06 Analytical Chemistry 25, (1397-1399) 1953: "Microdetermination of N-1-Naphthyl phthalamic Acid Residues in Plant Tissues." by A.E. Smith and G.M. Stone.
- GS-0183-07 JAOAC, 48, (776-778) 1965: "N-1-naphthylphthalamic Acid Residues in Food Crops" by R.H. Johnson
- GS-0183-08 EPA Index to Pesticide Chemicals

GS-0183-09 Agricultural Statistics, 1981: USDA, GPO, Washington, DC

GS-0183-10 Pesticide Petition No. 0F0904 (Acc. No. 116362) "Residues - Summary Sheet" for 1969, on cranberries

GS-0183-11 Pesticide Petition No. 0F0904 (Acc. No. 116361) "Response to Letter June 4, 1970."

GS-0183-12 Pesticide Petition No 0F2321 (Acc. No. 003252); ibid (400-75), June 19, 1979; ibid, (Acc. No. 008725) Addendum to Report No. 105.

GS-0183-13 Pesticide Petition No. 0F2321 (Acc. No. 008725); ibid Acc. No. 238629, June 19, 1979.

GS-0183-14 Agricultural Statistics, 1982: USDA, GPO, Washington, DC

GS-0183-15 A Lifetime Feeding Oncogenic Study in Mice. IRDC #399-002B. 7/23/82.

GS-0183-16 Fink, R., and Beavers, J. (1977) Acute Oral LD50 - Mallard Duck - Alanap technical. Final Report. Project No. 117-123. (Unpublished study received Nov. 30, 1977 under 400-49; prepared by Wildlife International Co., Ltd., submitted by Uniroyal Chemical Co., Bethany, CT)

APPENDIX II-3

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.
* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.	
NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.	

ATTACHMENT C DATA CALL-IN SUMMARY SHEET

EPA Registration No.: _____
Product Name: _____
Registrant's Name: _____
Date of Data Call-In Notice: _____

for products containing _____ as an active ingredient.
Note: For each registered product, a separate "Data Call-In Summary Sheet" must be filled in and sent to the Agency. If you qualify for a "generic" data exemption or have decided to voluntarily cancel/suspend your registration, check the appropriate box for Nos. 1 or 2.

1. ☐ I request a voluntary cancellation of this product's registration.
 2. ☐ I request an end-use exemption. Attached is a current, accurate Confidential Statement of my product's registration indicating my source of active ingredient or a certification on the "Generic Data Exemption Statement."
- If you select only Option 1 or 2 above, sign here, and return this page to EPA.

Dated _____ Signature of Authorized Representative _____

Telephone No. + area code _____ Name Typed or Printed _____ Address (if different from mailing address) _____

If you choose one or more of the following options (Nos. 3-12), you may choose different options for different data requirements, but for each data requirement, at least one box must be checked.

Options Nos. 3-5 for satisfying Notice's data requirements	Chronic Feeding		Oncogenicity		Teratogenicity		Reproductive
	Species #1	Species #2	Species #1	Species #2	Species #1	Species #2	
3. I am submitting existing data for each data requirement box which has been checked. A cover sheet (Attachment F) is attached which summarizes each study submitted.							
4. I will generate and submit data for each data requirement box which has been checked and submit progress reports according to the schedule in Section II. B. of this Notice. These data will be generated according to the pesticide Registration: Proposed Data Requirements regulation [], the OECD protocols [], or different protocol []. A completed coversheet (Attachment E) is attached.							
5. I have entered into an agreement under FIFRA 3(c)(2)(B)(ii) with one or more other Registrants to share the burdens of generating and submitting data and progress reports for each data requirement box which has been checked according to the schedule in Section II. of this Notice. A copy of the agreement is attached to the name and address of registrant to submit each test is specified.							

ATTACHMENT C (cont'd.)

Other Options 6 through 9	Chronic Feeding Species #1 Species #2	Oncogenicity Species #1 Species #2	Teratogenicity Species #1 Species #2	Reproductive
6. I claim that I am not obliged to arrange to submit the data required by this Notice for the following checked data requirement box(es) because the use(s) of my registered pesticide product are such that, under the Pesticide Registration: Proposed Data Requirements regulation, these data requirements do not apply to my product. Attached is an explanation of why my registered pesticide product is not subject to the Requirements together with a current and accurate Confidential Statement of my product's composition and current label for my registered pesticide product.				
7. I enclose a completed application to amend my registration by deleting one or more of its currently registered uses. Once this amendment is approved, I believe the data requirements in the checked box(es) will not apply to my product.				
8. I request a waiver from the obligation to arrange to submit data for the following checked data requirement box(es), because the active ingredient in my registered pesticide product is a low volume/minor chemical. Attached are the documents necessary for a low volume/minor chemical request according to Section III.				
9. I have submitted an offer as specified in Section III of the Notice but have been unsuccessful in entering into any agreement to share the burdens of generating data with other registrant(s) who is committed to generate the data. Attached are copies of the offers I have made regarding the requirements indicated by the checked data box(es). Also attached is proof of receipt of the offer(s).				

Dated

Signature of Authorized Representative

Typed or Printed

Telephone No. + area code

Address (if different from address)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No. _____ Guidance Document for _____

Date _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submit- ting Data (At- tached)	
\$158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk- density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Appendix III-1 (continued)

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submit- ting Data (At- tached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explosibility				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric break- down voltage				
\$158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitiza- tion				

Chapter I—Environmental Protection Agency

§ 162.10

cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(1)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 4, and 25 of FIFRA, as amended, 7 U.S.C. 136 et seq.)

(44 FR 27962, May 11, 1979)

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label*. Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(3) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label—(i) General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a

wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers—(A) Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by

any agency of the Federal Government.

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling.

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser.

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations.

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(5)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for . . ." "Distributed by . . ." or "Sold by . . ." to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement.*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients, and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.*

(i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(b) **Warnings and precautionary statements.** Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may

appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) **Required front panel statements.** With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD ₅₀	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC ₅₀	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2 thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD ₅₀	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000.	Greater than 20,000.
Eye effects	Corneal opacity; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive.	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(I) **Human hazard signal word—(A) Toxicity Category I.** All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) **Toxicity Category II.** All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) **Toxicity Category III.** All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) **Toxicity Category IV.** All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) **Use of signal words.** Use of any signal word(s) associated with a higher

Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(II) **Child hazard warning.** Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(III) **Statement of practical treatment—(A) Toxicity Category I.** A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the

placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(3) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Title 40—Protection of Environment

Size of label front panel in square inches	Points	
	Required type size, at least	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye contact effects
I	Fatal (immediate or delayed) if swallowed (breathed or absorbed through skin). Do not breathe vapor (dust or spray mist). Do not get in eyes, on skin, or on clothing. (Front panel statement of practical treatment required.)	Caustic, causes eye and skin damage (or skin irritation). Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling, handling or less if swallowed. (Appropriate first aid statement required.)
II	May be fatal if swallowed (breathed or absorbed through the skin). Do not breathe vapors (dust or spray mist). Do not get in eyes, on skin, or on clothing. (Appropriate first aid statement required.)	Causes eye (and skin) irritation. Do not get in eyes, on skin, or on clothing. Irritated if swallowed. (Appropriate first aid statement required.)
III	Irritated if swallowed (breathed or absorbed through the skin). Avoid breathing vapors (dust or spray mist). Avoid contact with skin (eyes or clothing). (Appropriate first aid statement required.)	Avoid contact with skin, eyes or clothing, in case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	(No precautionary statements required.)	(No precautionary statements required.)

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the

hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

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stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD₅₀ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC₅₀ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD₅₀ of 100 mg/kg or less, or a subacute dietary LC₅₀ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the

pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) Pressurized Containers	
Flash point at or below 25° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate. Exposure to temperatures above 130° F may cause bursting.
Flash point above 25° F and not over 60° F or if the flame distance is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers.	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
At or below 25° F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 25° F and not over 60° F.	Flammable. Keep away from heat and open flame.
Above 60° F and not over 130° F.	Do not use or store near heat or open flame.

(i) *Directions for Use—(1) General requirements—(i) Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on

printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended*



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for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repackaging for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

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(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum size as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(1) *Statement of Use Classification.* By October 22, 1978, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(1) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type

of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) *Advertising.* [Reserved]

(40 FR 22288, July 3, 1975; 40 FR 32228, Aug. 1, 1975; 40 FR 36871, Aug. 21, 1975, as amended at 41 FR 5788, Feb. 9, 1976)

§ 162.11 *Criteria for determinations of unreasonable adverse effects.*

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing—*

(1) *Presumption.* (1) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five

LABELING REQUIREMENTS OF THE RIPRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

APPENDIX IV-2 (continued)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (In red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

APPENDIX IV-2 (continued)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDSCriteriaRequired Label Statement

I. Pressurized Containers

- A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

- B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.

Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

- C. ALL OTHER PRESSURIZED CONTAINERS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

II. Non-Pressurized Containers

- A. Flashpoint at or below 20°F.

Extremely flammable. Keep away from fire, sparks, and heated surfaces.

- B. Flashpoint above 20°F and not over 80°F.

Flammable. Keep away from heat and open flame.

- C. Flashpoint over 80°F and not over 150°F.

Do not use or store near heat and open flame.

- D. Flashpoint above 150°F.

None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30.	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."
2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused ¹ , dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

¹/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewhere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)phthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentachlorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone	Formaldehyde
Acetonitrile	Formic acid
Acetophenone	Isobutyl alcohol
Acrylic acid	Maleic anhydride
Aniline	Methyl alcohol (methanol)
Benzene	Methyl ethyl ketone
Chlorobenzene	Methyl methacrylate
Chloroform	Naphthalene
Cyclohexane	Saccharin and salts
Cyclohexanone	Thiourea
Dichlorodifluoromethane (Freon 12®)	Toluene
Diethyl phthalate	1,1,1-Trichloroethane
Dimethylamine	1,1,2-Trichloroethane
Dimethyl phthalate	Trichlorofluoromethane (Freon 11®)
1,4-Dioxane	Vinyl chloride
Ethylene oxide	Xylene